

DT04 Rec'd PCT/PTO 07 SEP 2004

LISTING OF CLAIMS

1. *(currently amended)*: A method for producing mononuclear cells overexpressing IL-10, comprising wherein the method comprises the steps of:
  - (a) providing a composition comprising mammalian peripheral blood mononuclear cells ~~(from a mammal)~~ wherein, if the cells comprise lymphocytes, the lymphocytes are not selected or enriched on the basis of their antigen specificity;
  - (b) introducing into at least a fraction of said mononuclear cells an expression construct comprising that comprises a nucleotide sequence encoding an IL-10 polypeptide ~~having IL-10 activity into at least part of the mononuclear cells;~~ and,
  - (c) recovering recovery of mononuclear cells that overexpressing the polypeptide having IL-10 activity,
2. *(currently amended)*: A method according to claim 1, wherein an enriched fraction or subset of said composition comprising peripheral blood mononuclear cells are provided. ~~enriched for a subfraction of the peripheral blood mononuclear cells.~~
3. *(currently amended)*: A method according to claim 2, wherein the enriched fraction ~~subfraction of mononuclear cells~~ is selected from the group consisting of lymphocytes or a subset thereof, B-cells, T-cells, CD4<sup>+</sup>-cells, macrophages, monocytes or dendritic cells (DC).
4. *(currently amended)*: A method according to claim 1 ~~any one of claims 1—3~~, wherein prior to step (b), the mononuclear cells are induced to, or allowed to, proliferate[[d]].
5. *(currently amended)*: A method according to claim 4, wherein the mononuclear cells are induced to proliferate[[d]] ~~by in the presence of a proliferating agent.~~
6. *(currently amended)*: A method according to claim 5, wherein the proliferating agent is at least one or more of
  - (a) an anti-CD3 antibody;
  - (b) [[/]] an anti-CD28 antibody; or
  - (c) phytohemagglutinin PHA.

7. *(currently amended)*: A method according to ~~any one of~~ claim 1 ~~[[ - 6]]~~, wherein subsequent to step (b), the mononuclear cells are fractionated to yield an enriched for a fraction or subset subfraction thereof mononuclear cells.

8. *(currently amended)*: A method according to claim 7, wherein the ~~subfraction~~ fraction or subset of mononuclear cells is selected from the group consisting of comprises enriched

- (i) lymphocytes or a subset thereof, B cells, T cells, CD4<sup>+</sup> cells,
- (ii) macrophages or monocytes, or
- (iii) dendritic cells (DC).

9. *(currently amended)*: A method according to claim 1 ~~any one of claims 1—8~~, wherein subsequent to step (b), the mononuclear cells are enriched for cells that overexpress ~~(over)expressing~~ the nucleotide sequence IL-10 transgene.

10. *(currently amended)*: A method for producing a pharmaceutical composition comprising mononuclear cells overexpressing IL-10, which method comprises combining mixing

- (a) the mononuclear cells overexpressing IL-10 produced in accordance with claim 1 obtained in above claims

with

- (b) an acceptable suitable pharmaceutical carrier.

11. *(currently amended)*: A composition comprising mononuclear cells that comprise ~~containing~~ an IL-10 transgene.

12. *(currently amended)*: A composition according to claim 11, wherein whereby the mononuclear cells composition comprise[[s]] T cells that comprise said ~~containing an~~ IL-10 transgene.

13. *(currently amended)*: A composition according to claim 12, wherein whereby the T cells functionally phenotypically mimic regulatory T cells in that they T cells inhibit:

- (a) decrease proliferation of autologous responder cells, and/or
- (b) decrease production of ~~[[the]]~~ pro-inflammatory cytokine IL-12 by dendritic cells.

14. *(currently amended)*: A pharmaceutical composition comprising the composition according to claim 11 ~~any one of claims 11—13, wherein the composition is a pharmaceutical composition comprising in addition to the mononuclear cells~~ and a pharmaceutically acceptable carrier.
15. *(currently amended)*: A method of treating a disease or condition associated with undesired activation and/or expansion of T cells, which ~~wherein the method comprises administering an effective amount of a pharmaceutical composition according to claim 14 to a subject suffering from said [[a]] disease~~ or condition associated with undesired activation and/or expansion of T cells.
16. *(currently amended)*: A method according to claim 15, wherein the disease or condition associated with undesired activation and/or expansion of T cells is a Th1-mediated disease or condition.
17. *(currently amended)*: A method according to claim 16, wherein the Th1-mediated disease or condition is ~~selected from the group consisting of Crohn's disease, reactive arthritis, insulin-dependent diabetes, colitis, pancreatitis, an~~ inflammatory lung disease, an inflammatory eye disease, multiple sclerosis, Hashimoto's thyroiditis, Graves' Grave's disease, chronic articular rheumatism, contact dermatitis, psoriasis, graft rejection, graft-versus-host disease, or ~~and~~ sarcoidosis.

**CANCEL Claims 18 and 19**

20. *(new)* A method according to claim 3 wherein the lymphocyte subset comprises an enriched population of B cells, T cells or CD4+ cells.
21. *(new)* A method according to claim 8 wherein the lymphocytes subset comprises an enriched population of B cells, T cells or CD4+ cells.
22. *(new)* The method of claim 9 wherein said overexpressed nucleotide sequence encodes IL-10.
23. *(new)* A method according to claim 16 wherein the Th1-mediated disease is an inflammatory disease.